UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/792,273	03/04/2004	Ruey J. Yu	59210.000046	4235

21967 7590 10/25/2006

HUNTON & WILLIAMS LLP
INTELLECTUAL PROPERTY DEPARTMENT
1900 K STREET, N.W.
SUITE 1200
WASHINGTON, DC 20006-1109

EXAMINER	
ROYDS, LESLIE A	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 10/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/792,273	YU ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-55 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-55 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-55 are presented for examination.

The Examiner acknowledges Applicant's Petition to Make Special filed and granted pursuant to MPEP §708.02(IV).

Applicant is reminded that the petition has been granted contingent upon Applicant's election without traverse of a single invention in the event that, during examination, the claims are found to encompass more than one patentable invention. Failure to make an election without traverse will void the special status accorded in the petition.

Pursuant to MPEP §812.01, election was not pursued via telephone due to the complexity of the present restriction requirement.

Requirement for Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 2-4, drawn to a composition comprising an alkaline pharmaceutical drug and an alkyl alpha hydroxyacid, classified in class 514, subclasses 553 or 557, depending on the acid used.

II. Claim 5-8, drawn to a composition comprising an alkaline pharmaceutical drug and an araalkyl hydroxyacid, classified in class 514, subclasses 553 or 557, depending on the acid used.

III. Claims 9-10, drawn to a composition comprising an alkaline pharmaceutical drug and an polycarboxy alpha hydroxyacid, classified in class 514, subclasses 553 or 574, depending on the acid used.

IV. Claims 11-12, drawn to a composition comprising an alkaline pharmaceutical drug and a beta hydroxyacid, classified in class 514, subclasses 553 or 557, depending on the acid used.

V. Claims 15-16, drawn to a composition comprising an alkaline pharmaceutical drug and an aldonic acid, classified in class 514, subclasses 553 or 557, depending on the acid used.

VI. Claims 17-18, drawn to a composition comprising an alkaline pharmaceutical drug and an aldaric acid, classified in class 514, subclasses 553 or 557, depending on the acid used.

VII. Claims 19-20, drawn to a composition comprising an alkaline pharmaceutical drug and an alduronic acid, classified in class 514, subclasses 553 or 557, depending on the acid used.

VIII. Claims 21-22, drawn to a composition comprising an alkaline pharmaceutical drug and an aldobionic acid, classified in class 514, subclasses 553 or 557, depending on the acid used.

IX. Claims 24-25, drawn to a composition comprising an alkaline pharmaceutical drug and an alpha ketoacid, classified in class 514, subclasses 553 or 557, depending on the acid used.

X. Claim 26, drawn to a composition comprising an alkaline pharmaceutical drug and a miscellaneous hydroxyacid, classified in class 514, subclasses 553 or 557, depending on the acid used, depending on the hydroxyacid used.

XI. Claims 27-28, drawn to a composition comprising an alkaline pharmaceutical drug and an oligomer of hydroxyacid, classified in class 514, subclasses 553 or 557, depending on the acid used.

XII. Claims 37-46, drawn to a method of forming a molecular complex between an alkaline pharmaceutical drug and at least one of a hydroxyacid, polyhydroxyacid, related acid and lactone, classified in class 514, subclasses 381, 553, 557 or 574 or class 424, subclass 401, for example, depending on the composition used.

XIII. Claim 47-55, drawn to a method of treating a cosmetic condition or dermatologic indication in a subject comprising topically administering a therapeutically effective amount of a composition comprising a composition according to claim 1, classified in class 514, subclasses 381, 553, 557 or 574 or class 424, subclass 401, for example, depending on the composition used.

Claims 1 and 29-36 link Inventions I-IV, claims 1, 13-14 and 29-36 link Inventions V-VII and claims 1, 23 and 29-36 link Inventions VIII-XI. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1 and 29-36 or claims 1, 13-14 and 29-36 or claims 1, 23 and 29-36. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. Please reference *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP §804.01.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-XI and XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the presently claimed product(s) (i.e., a composition comprising a molecular complex formed between an alkaline pharmaceutical and at least one hydroxyacid, polyhydroxy acid, related acid or lactone) can be

used in materially different processes of use, namely the treatment of acne or the treatment of dandruff, for example.

Inventions I-XI and XII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the claimed composition comprising a molecular complex formed between an alkaline pharmaceutical and at least one hydroxyacid, polyhydroxy acid, related acid or lactone can be produced by forming a molecular complex of a pharmaceutical agent and an alpha hydroxyacid and a complexing agent, which comprises an organic amino compound in free base form having one or more other functional groups with unshared electrons (see U.S. Patent No. 5,877,212).

Inventions XII and XIII are patentably distinct. Inventions are patentably distinct if it can be shown that they have different modes of operation, different functions, or different effects and different resultant endpoints (See MPEP § 806.04, MPEP § 808.01). In the instant case, it is noted that the ultimate objective of Invention XII (i.e., producing a molecular complex) is distinct from the objective of Invention XIII (i.e., treating a cosmetic condition) such that the endpoints and steps required to execute either of Inventions XII or XIII are distinctly different from one another. In other words, the Invention of Group XII can be executed without executing the Invention of Group XIII. As a result, the discovery of one of Inventions XII or XIII would not anticipate, suggest or render obvious the other invention and, thus, the inventions are properly held to be patentably distinct from one another.

Inventions I through XI are also patentably distinct. Inventions are patentably distinct if it can be shown that they have different modes of operation, different functions, or different effects and different resultant endpoints (See MPEP § 806.04, MPEP § 808.01). In the instant case, each of the compositions of Groups I through XI are chemically and structurally distinct from one another such that the active

agents required to form each of the compositions of each of the groups are distinctly different from one another such that the discovery of one would not anticipate, suggest or render obvious the others and, thus, the compositions are properly held to be patentably distinct from one another.

Because these inventions are independent or distinct for the reasons given above, they require a different field of search (see MPEP § 808.02) and they have acquired a separate status in the art because of their recognized divergent subject matter, the requirement for election for examination purposes as indicated is proper.

Election of Species Requirement

This application contains claims directed to the following patentably distinct species of (a) alkaline pharmaceutical drug (claim 30), (b) alkyl alpha hydroxyacid (claim 4), (c) aralkyl hydroxyacid (claim 8), (d) polycarboxy alpha hydroxyacid (claim 10), (e) beta hydroxyacid (claim 12), (f) aldonic acid (claim 16), (g) aldaric acid (claim 18), (h) alduronic acid (claim 20), (i) aldobionic acid (claim 22), (j) alpha ketoacid (claim 25), (k) miscellaneous hydroxyacid (claim 26), (l) oligomer of hydroxyacid (claim 28), (m) additional pharmaceutical or topical agents (claims 35-36) and (n) cosmetic conditions or dermatological indications (claims 53-55).

The species are independent or distinct because:

The species of compounds recited in the present claims [species (a)-(m)] are structurally and/or chemically distinct from any one other compound encompassed by the present claims such that a comprehensive search of the patent and non-patent literature for any one such compound would not necessarily result in a comprehensive search of any one or more of the other compounds recited in the claims. Notwithstanding that Applicant may have established an underlying common function to this broad genus of compounds, namely, that they are capable of amenable for forming a molecular complex, it remains that the art does not necessarily recognize such a shared function as being common to each of the variety of distinct compounds encompassed by the claims. Furthermore, the disparate nature and

variability encompassed by this broad genus of compounds precludes a quality examination on the merits not only because a burdensome search would be required for the entire scope of the claim(s), but also because consideration of the findings of such a search for compliance with the statutes and requirements set forth under 35 U.S.C. 101, 102, 103 and 112 would be unduly onerous. In addition, the discovery of any one of the presently claimed compounds for use in a composition would not necessarily anticipate or reasonably suggest or render obvious the use of any one or more of the other compounds claimed for the same objective.

The species of cosmetic conditions or dermatologic indications are independent or distinct because each are distinct from one another in etiology, pathophysiological manifestations, treatment protocol (i.e., duration of treatment, dosage amounts of pharmaceutical agents to be administered, frequency of treatment, etc.) and patient population such that a comprehensive search of the patent and non-patent literature for any one such disorder or condition would not necessarily result in a comprehensive search of any one or more of the other disorders or conditions recited in the present claims. It remains that the art does not necessarily recognize a shared characteristic as being common to each of the disparate disorders encompassed by the claim. For these reasons, they are, therefore, considered patentably distinct. It is noted that the discovery of the treatment of any one of the presently claimed disorders or conditions using a composition of the type presently claimed would not necessarily anticipate, reasonably suggest or render obvious the treatment of any one or more of the other disorders or conditions of the present claims for the same reasons described above.

Election of species should be made consistent with the following instructions:

(i) Election of Group I requires the election of a single disclosed species of (a) alkaline pharmaceutical drug (claim 30) and (b) alkyl alpha hydroxyacid (claim 4);

(ii) Election of Group II requires the election of a single disclosed species of (a) alkaline pharmaceutical drug (claim 30) and (c) aralkyl hydroxyacid (claim 8);

(iii) Election of Group III requires the election of a single disclosed species of (a) alkaline pharmaceutical drug (claim 30) and (d) polycarboxy alpha hydroxyacid (claim 10);

(iv) Election of Group IV requires the election of a single disclosed species of (a) alkaline pharmaceutical drug (claim 30) and (e) beta hydroxyacid (claim 12);

(v) Election of Group V requires the election of a single disclosed species of (a) alkaline pharmaceutical drug (claim 30) and (f) aldonic acid (claim 16);

(vi) Election of Group VI requires the election of a single disclosed species of (a) alkaline pharmaceutical drug (claim 30) and (g) aldaric acid (claim 18);

(vii) Election of Group VII requires the election of a single disclosed species of (a) alkaline pharmaceutical drug (claim 30) and (h) alduronic acid (claim 20);

(viii) Election of Group VIII requires the election of a single disclosed species of (a) alkaline pharmaceutical drug (claim 30) and (i) aldobionic acid (claim 22);

(ix) Election of Group IX requires the election of a single disclosed species of (a) alkaline pharmaceutical drug (claim 30) and (j) alpha ketoacid (claim 25);

(x) Election of Group X requires the election of a single disclosed species of (a) alkaline pharmaceutical drug (claim 30) and (k) miscellaneous hydroxyacid (claim 26);

(xi) Election of Group XI requires the election of a single disclosed species of (a) alkaline pharmaceutical drug (claim 30) and (l) oligomer of hydroxyacid (claim 28);

(xii) Election of Group XII requires the election of a single disclosed species of (a) alkaline pharmaceutical drug (claim 30) **and** a single disclosed species from any one of (b) alkyl alpha hydroxyacid (claim 4) or (c) aralkyl hydroxyacid (claim 8) or (d) polycarboxy alpha hydroxyacid (claim 10) or (e) beta hydroxyacid (claim 12) or (f) aldonic acid (claim 16) or (g) aldaric acid (claim 18) or (h) alduronic acid (claim 20) or (i) aldobionic acid (claim 22) or (j) alpha ketoacid (claim 25) or (k) miscellaneous hydroxyacid (claim 26) or (l) oligomer of hydroxyacid (claim 28); or

(xiii) Election of Group XIII requires the election of a single disclosed species of (a) alkaline pharmaceutical drug (claim 30) **and** a single disclosed species from any one of (b) alkyl alpha hydroxyacid (claim 4) or (c) aralkyl hydroxyacid (claim 8) or (d) polycarboxy alpha hydroxyacid (claim 10) or (e) beta hydroxyacid (claim 12) or (f) aldonic acid (claim 16) or (g) aldaric acid (claim 18) or (h) alduronic acid (claim 20) or (i) aldobionic acid (claim 22) or (j) alpha ketoacid (claim 25) or (k) miscellaneous hydroxyacid (claim 26) or (l) oligomer of hydroxyacid (claim 28) **and** a single disclosed species of (n) cosmetic conditions or dermatological indications (claims 53-55).

Election of any one of Groups I-XI provides Applicant the opportunity to also elect, if he so wishes, an single disclosed species of additional pharmaceutical or topical agent selected from (m) additional pharmaceutical or topical agents (claims 35-36) to be included in the composition. This is an optional election.

Applicant is cautioned that the election of a particular combination of species, wherein the elected combination of agents is not adequately supported by the accompanying specification, may raise an issue of new matter under the written description requirement of 35 U.S.C. 112, first paragraph.

Applicant is also reminded that a proper reply to this election will include the identification of the exact page and line number that supports the elected specie(s).

Currently, claims 1-55 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species of agents that are elected consonant with this requirement and a listing of all claims readable thereon the elected species of agents, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic

claim as provided by 37 CFR 1.141. If claims are added after the election, Applicant must indicate which are readable upon the elected species. Please reference MPEP §809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though this requirement be traversed (37 C.F.R. 1.143) and (ii) an identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should Applicant traverse on the ground that the inventions or species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP §821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 C.F.R. 1.116; amendments submitted after allowance are governed by 37 C.F.R. 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for

patentability in accordance with 37 C.F.R. 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. §103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicants are advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the Examiner withdraws the restriction requirement before the patent issues. See MPEP §804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie A. Royds
Patent Examiner
Art Unit 1614

October 17, 2006

Ardin H. Marschel 10/22/06
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER